REMARKS

Claims 39 and ~~41-47~~ remain pending in this application. Claims 1-38 and ~~40-43~~ were previously canceled. Applicants reserve the right to file one or more continuation, divisional, or continuation-in-part applications directed to any canceled subject matter. No new matter is added in this amendment.

I. The Rejection Under 35 U.S.C. § 102(b) Should be Withdrawn

Claim 39 is rejected on pages 2-3 of the office action under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. patent number 6,232,346 to Sole et al. ("Sole"). According to the office action,

> [t]he reference does not specifically define that treating functional deterioration associated with ageing encompass 'inhibiting the loss of learning ability or increasing the learning ability', however it would be inherent outcomes since the reference teaches the same method step comprising administering the same composition to the same patient population as the instant claim. It is noted that products of identical chemical composition cannot have mutually exclusive properties.

(*See* office action at page 3).

Applicants respectfully traverse the rejection as improper under the law as set forth by the Federal Circuit in *Jansen v. Rexall Sundown* and *Rapoport v. Dement*, which are discussed below.

The pending claims encompass methods for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment comprising feeding the pet a mixture of antioxidants at levels sufficient to accomplish the said inhibiting or increasing, the mixture of antioxidants comprising Vitamin E, Vitamin C and at least one antioxidant selected from the group consisting of alpha lipoic acid, L-carnitine and mixtures thereof.

Applicants submit that the claims recite the language "in need of." The subject matter recited in the pending claims is not anticipated, based upon the cited reference, because the Office has failed to show that there was an intent to use the compositions

for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment. As admitted in the office action, the reference does not specifically define that treating functional deterioration associated with ageing encompass inhibiting the loss of learning ability or increasing the learning ability. When a claim recites a method of treating a disorder to be performed on a patient 'in need of' such treatment, the proper construction of the claim is that the method be practiced in order to treat that specific disorder. *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1333-34, 68 U.S.P.Q.2d 1154, 1157-58 (Fed. Cir. 2003); *Rapoport v. Dement*, 254 F.3d 1053, 1060-61 (Fed. Cit. 2001). In *Rapoport v. Dement*, the claim under dispute recited:

> A method of treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . .

254 F.3d at 1060. The court reasoned that the phrase "to a patient in need of such treatment" in the body of the claim would not have a proper antecedent basis without treating the claim preamble as claim feature. *Id.* at 1059. The court further explained that this claim feature required that the azapirone compound be administered in order to treat sleep apneas. *Id.* at 1060-61 (analyzing whether an allegedly anticipatory reference disclosed administration of an azapirone compound with intent to cure sleep apneas and stating that the reasons for administering the compound were relevant to an anticipation analysis). A subsequent Federal Circuit decision confirmed the conclusion of the *Rapoport* court. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (confirming that the Rapoport method of treatment claim required that the method be practiced in order to treat sleep apneas).

In *Jansen*, a similar method of treatment claim was interpreted to require that a drug combination be administered in order to treat the specified disorder. *Id.* In *Jansen*, the claim under dispute recited:

> 1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by

> either folic acid deficiency or by vitamin B12 deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid.

Id. at 1330, 68 U.S.P.Q.2d at 1155. Relying in part on the *Rapoport* decision, the court interpreted the claim preamble as a statement of the "intentional purpose for which the method must be performed," rather than "a statement of effect that may or may not be desired or appreciated," thus rendering the preamble as an element of the claim. *Id.* at 1333, 68 U.S.P.Q.2d at 1158. That the specific type of anemia and the "in need" language was added to the claim during prosecution to achieve allowance of the claim bolstered the court's conclusion that the two phrases should be read together and considered an element of the claim. *Id.* at 1334, 68 U.S.P.Q.2d at 1158. As stated by the court:

> . . .that "need" must he recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances or their addition suggest they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megoblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention.

Id. at 1334, 68 U.S.P.Q.2d at 1158. Accordingly, a method claim further reciting "in need thereof" language should be properly construed such that the method is practiced with intent to reduce the particular disorder or symptom recited in the claim.

Here, as in *Jansen* and *Rapoport*, the pending claims recite that the methods are used on animals "in need of." There is nothing in the reference that discloses an intent to inhibit the loss of learning ability or increase the learning ability of an aged companion pet in need of such treatment.

Accordingly, Sole does not anticipate the claimed invention. Therefore, Applicants respectfully request that the rejection of claim 39 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

II. The Rejections Under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 39 and 44-47 are rejected on pages 4-7 of the office action under 35 U.S.C. § 103(a) as allegedly obvious over Sole in view of Hagen et al., FASEB J., 13:411-418, Feb. 1999 ("Hagen"). According to the office action,

> [t]he reference [Sole] does not specifically define that treating functional deterioration associated with ageing encompass 'inhibiting the loss of learning ability or increasing the learning ability', however it would be inherent outcomes since the reference teaches the same method step comprising administering the same composition to the same patient population as the instant claim. It is noted that products of identical chemical composition cannot have mutually exclusive properties.

(*See* Office Action at page 5).

The office action further states that Hagen "discloses feeding α-lipoic acid (0.5% w/w = 5000 ppm) to old rats for 2 weeks restores mitochondrial function, lowers oxidants to the level of a young rats [sic] and increases ambulatory activity (abstract)." (*Id.*). It further teaches that lipoic acid supplementation improves indices of metabolic activity as well as lowers oxidative stress and damage evident in aging (abstract). (*Id.*).

Applicants respectfully traverse the rejection for at least the following reasons.

The pending claims encompass methods for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment comprising feeding the pet a mixture of antioxidants at levels sufficient to accomplish the said inhibiting or increasing, the mixture of antioxidants comprising Vitamin E, Vitamin C and at least one antioxidant selected from the group consisting of alpha lipoic acid, L-carnitine and mixtures thereof.

It should be noted that neither reference teaches or suggests methods for inhibiting the loss of learning ability or increasing the learning ability of an aged

companion pet in need of such treatment, and it is axiomatic that the cited references must teach each and every element of the claimed invention to establish a case of prima facie obviousness. Therefore, the cited references can not, by law, render the claimed invention obvious. To account for this lack of disclosure among the cited references, the Examiner states that "[s]ince L-carnitine, Vitamin E, C, and α-lipoic acid are taught to be effective for improving age-related functional deterioration and lower oxidative stress, one of ordinary skill in the art would reasonably expect the combination of those anti-oxidants not only to inhibit oxidative stress associated with ageing but also to counteract age-related loss of learning ability and improve mental acuity in the aged cats and dogs." (*See* Office Action at page 6).

Applicants respectfully submit that the Examiner has failed to provide the legally required nexus between inhibiting oxidative stress disclosed in the reference and claimed method of counteracting age-related loss of learning ability and improve mental acuity. Indeed, as set forth above, there is nothing in the cited references or the knowledge of one of ordinary skill in the art that would show that there was an intent to use the compositions in the cited references for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment. As the Examiner is aware, when a claim recites a method of treating a disorder to be performed on a patient 'in need of' such treatment, the proper construction of the claim is that the method be practiced in order to treat that specific disorder. *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1333-34, 68 U.S.P.Q.2d 1154, 1157-58 (Fed. Cir. 2003); *Rapoport v. Dement*, 254 F.3d 1053, 1060-61 (Fed. Cit. 2001).

Applicants respectfully submit that the claims are directed to methods for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment. The combination of references fails to disclose or suggest the intent to treat the specific disorder as claimed. The Office Action fails to provide the motivation to modify the teachings of the references to obtain the claimed invention. Indeed, absent a showing of the specific intent to use the

compositions disclosed in the cited references for the claimed purpose recited in the method claims, the claims cannot be obvious in view of the cited art.

Therefore, Applicants respectfully request that the rejection of claims 39 and 44-47 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

III. The Rejections Under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 39 and 44-47 are rejected on pages 7-10 of the office action under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,916,912[1] (issued date 6/29/1999) ("the '912 patent") in view of Shigenaga et al., Proc Natl Acad Sci USA, 91:10771-10778, 1994 ("Shigenaga"). Applicants respectfully traverse the rejection for at least the following reasons.

Applicants respectfully point out that each of the references fails to teach or suggest methods for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment, and it is axiomatic that the cited references must teach each and every element of the claimed invention to establish a case of prima facie obviousness. Therefore, the cited references can not, by law, render the claimed invention obvious.

The office action alleges that the '912 patent "teaches a method for increasing the metabolic rate of aged cells without concomitant increase in metabolic production of reactive species comprising orally administering to a mammalian host an effective dosage of at least about 10 mg/kg (10ppm) host/day of a carnitine and at least about 10 mg/kg (10 ppm) host/day of a mitochondrially active antioxidant such as lipoic acid." (*See* office action at page 7). However, as the Examiner is aware the administration of a combination of substances for a different use is not a teaching or suggestion of administering such substances in a method for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment. The office action further alleges that the '912 patent teaches that two reagents given to old

[1] Applicants point out that the Examiner inadvertently cited U.S. patent number 5,915,912 in the office action and not U.S. patent number 5,916,912, which appears on the list of references cited by the Examiner. Applicants' response is directed to the correct citation (*i.e.*, U.S. patent number 5,916,912).

animals restored all three mitochondrial functions and reversed several gross indicia of aging, including activity. (*See* office action at page 7). However, when a claim recites a method of treating a disorder to be performed on a patient 'in need of' such treatment, the proper construction of the claim is that the method be practiced in order to treat that specific disorder. *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1333-34, 68 U.S.P.Q.2d 1154, 1157-58 (Fed. Cir. 2003); *Rapoport v. Dement*, 254 F.3d 1053, 1060-61 (Fed. Cit. 2001).

Applicants respectfully submit that the combination of references fails to disclose or suggest the claimed method of counteracting age-related loss of learning ability and improve mental acuity. Indeed, there is nothing in the cited references or the knowledge of one of ordinary skill in the art that would show that there was an intent to use the compositions in the cited references for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment.

Applicants respectfully submit that the claims are directed to methods for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment. The combination of references fails to disclose or suggest the intent to treat the specific disorder as claimed. The Office Action fails to provide the motivation to modify the teachings of the references to obtain the claimed invention. Indeed, absent a showing of the specific intent to use the compositions disclosed in the cited references for the claimed purpose recited in the method claims, the claims cannot be obvious in view of the cited art.

Accordingly, Applicants respectfully request that the rejection of claims 39 and ~~41~~-47 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

There being no other rejections of record, Applicants believe that the claims are now in an allowable condition and respectfully request an early Notice of Allowance.

The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

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